

**2. RESPONSE/REMARKS**

**2.1 STATUS OF THE CLAIMS**

*Claims 1-24 were pending at the time of the Action.*

*Claim 1 has been amended herein.*

*Claims 10, 17 and 18 have been canceled without prejudice or disclaimer.*

*Claims 1-9, 11-16 and 19-24 remain pending in the case.*

Applicants appreciate the finding by the Examiner that all pending claims possess utility, are definite, fully enabled, and free of the prior art. Applicants further appreciate the Examiner's rejoinder of the species illustrated in claims 4-5 and 15-16 in view of an allowable generic linking claim.

**2.2 THE REJECTION OF CLAIMS UNDER 35 U. S. C. §112, 2<sup>ND</sup> PARAGRAPH, IS MOOT.**

*The Action at page 3 rejected claims 17 and 18 under 35 U. S. C. § 112, 2<sup>nd</sup> paragraph, allegedly as being indefinite.*

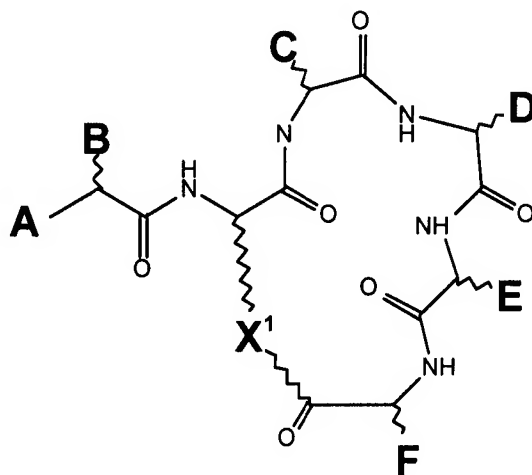
Applicants respectfully traverse. However, without acquiescing in any way with the propriety or substance of the rejection, mindful of patent term considerations, and the potential costs of a protracted prosecution, Applicants have elected to cancel claims 17 and 18, thereby rendering the present rejection moot. Applicants respectfully request, therefore, that the rejection be withdrawn.

**2.3 THE REJECTION OF CLAIMS UNDER 35 U. S. C. §112, 1<sup>ST</sup> PARAGRAPH, IS OVERCOME.**

*The Action at pages 4-7 rejected claims 1-24 under 35 U. S. C. § 112, 1<sup>st</sup> paragraph, allegedly as lacking enablement.*

*The Action considers that the Specification, while enabling for methods of treating inflammatory bowel disease mediated by the C5a receptor using a C5a receptor antagonist, does not provide enablement for such methods using any G-protein coupled receptor antagonist.*

Applicants respectfully traverse. However, without acquiescing in any way with the propriety or substance of the rejection, and mindful of patent term considerations and the potential costs of a protracted prosecution, Applicants have clarified the language of claim 1 to more particularly point out certain aspects of the present invention, namely “(a) method of treatment of inflammatory bowel disease, comprising the step of administering an effective amount of an inhibitor of a C5a receptor to a subject...” in need thereof, in which the inhibitor is a C5a receptor antagonist, that has substantially no agonist activity, and is a cyclic peptide or peptidomimetic compound of Formula I:



where A is H, alkyl, aryl, NH<sub>2</sub>, NH-alkyl, N(alkyl)<sub>2</sub>, NH-aryl, NH-acyl, NH-benzoyl, NHSO<sub>3</sub>, NHSO<sub>2</sub>-alkyl, NHSO<sub>2</sub>-aryl, OH, O-alkyl, or O-aryl; B is an alkyl, aryl, phenyl, benzyl, naphthyl or indole group, or the side chain of a D- or L-amino acid, but is not the side chain of glycine, D-phenylalanine, L-homophenylalanine, L-tryptophan, L-homotryptophan, L-tyrosine, or L-homotyrosine; C is the side chain of a D-, L- or homo-amino acid, but is not the side chain of

isoleucine, phenylalanine, or cyclohexylalanine; D is the side chain of a neutral D-amino acid, but is not the side chain of glycine or D-alanine, a bulky planar side chain, or a bulky charged side chain; E is a bulky substituent, but is not the side chain of D-tryptophan, L-N-methyltryptophan, L-homophenylalanine, L-2-naphthyl L-tetrahydroisoquinoline, L-cyclohexylalanine, D-leucine, L-fluorenylalanine, or L-histidine; F is the side chain of L-arginine, L-homoarginine, L-citrulline, or L-canavanine, or a bioisostere thereof; and X is  $-(CH_2)_nNH-$  or  $(CH_2)_nS-$ , where n is an integer of from 1 to 4;  $-(CH_2)_2O-$ ;  $-(CH_2)_3O-$ ;  $-(CH_2)_3-$ ;  $-(CH_2)_4-$ ;  $-CH_2COCHRNH-$ ; or  $-CH_2CHCOCHRNH-$ , where R is the side chain of any common or uncommon amino acid.

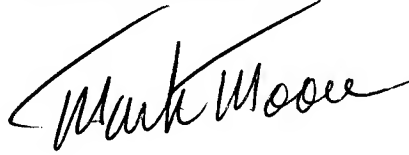
Applicants believe that the clarification of the language of claim 1 fully addresses any concerns raised by the Examiner with respect to enablement of the claimed invention, and therefore respectfully request that the rejection be withdrawn.

## **2.4 CONCLUSION**

Applicants believe that the present paper is fully responsive to the outstanding Action, and that the pending claims are in condition for allowance. As such, a Notice of Allowance and Issue Fee Due is earnestly sought from the Office in response to the present submission.

Should any issues remain outstanding upon consideration of the present paper and entry of the foregoing amendment, or should the Examiner have any questions or concerns, a telephone call to the undersigned Applicants' representative at the Examiner's convenience *prior to the issuance of any subsequent Official Action* would be sincerely appreciated.

Respectfully submitted,

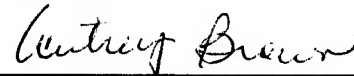


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